4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 528

[Docket No. FDA-2015-N-0002]

New Animal Drugs in Genetically Engineered Animals; opAFP-GHc2 Recombinant Deoxyribonucleic Acid Construct

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency) is amending the animal drug regulations to reflect the approval of a new animal drug application (NADA) filed by AquaBounty Technologies, Inc. The NADA provides for use of a recombinant deoxyribonucleic acid (rDNA) gene construct in a lineage of genetically engineered Atlantic salmon.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV-2), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8247, email: abig@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754 filed NADA 141-454 for an opAFP-GHc2 rDNA construct at the α-locus in the EO-1α lineage triploid, hemizygous, all-female Atlantic salmon (Salmo salar) known as AQUADVANTAGE Salmon. Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators. The NADA is

approved as of November 19, 2015, and the regulations are amended in 21 CFR part 528 to reflect the approval.

In addition, AquaBounty Technologies, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application (FOI Summary) may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an environmental assessment (EA), may be seen in the Division of Dockets Management (address in the previous paragraph) between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the FOI Summary, EA, and FONSI at the Center for Veterinary Medicine FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm. Patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 528

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 528 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "AquaBounty Technologies, Inc." and in the table in paragraph (c)(2), numerically add an entry for "086053" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754	086053
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086053	AquaBounty Technologies, Inc., Two Clock Tower Pl., suite 395, Maynard, MA 01754
	* * *
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PART 528--NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

3. The authority citation for 21 CFR part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Add § 528.1092 to read as follows:

§ 528.1092 opAFP-GHc2 recombinant deoxyribonucleic acid construct.

(a) Specifications. A single copy of the α-form of the opAFP-GHc2 recombinant deoxyribonucleic acid (rDNA) construct at the α-locus in the EO-1 α lineage of triploid, hemizygous, all-female Atlantic salmon (Salmo salar).

(b) Sponsor. See No. 086053 in § 510.600 of this chapter.

(c) Indications for use. Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) Limitations. These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

Dated: November 19, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2015-29902 Filed: 11/23/2015 8:45 am; Publication Date: 11/24/2015]